

EFFICACY REVIEW

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Product(s): Assault All Weather Bait

Date: September 15, 2005

EPA Reg No(s): 67517-66

DP Bar code(s): D287919

Chemical Code: Bromethalin 112802

Formulation(s): Bromethalin Baits (Blocks)

Purpose for Review: The purpose for this review is to determine if the previously submitted efficacy tests dated May 24, 1993, April 16, 1994, and April 26, 1994, are acceptable for reregistration of the above named product(s).

MRID No(s): 428295-02C Dickerson, C. W. May 24, 1993. Testing of a Paraffinized Block Rodenticide in Wild House Mice. Volume 3. Experiment #62-908. Purina Mills, Inc. Unpublished Report. OPP Designation 1.214. 48pp.

428643-01C Dickerson, C. W. May 24, 1993. Testing of a Paraffinized Block Rodenticide in Wild House Mice. Volume 4. Experiment #62-909. Purina Mills, Inc. Unpublished Report. OPP Designation 1.214. 48pp.

428295-03C Dickerson, C. W. May 24, 1993. Testing of a Paraffinized Block Rodenticide with Wild Norway Rats. Volume 5. Experiment #62-920. Purina Mills, Inc. Unpublished Report. OPP Designation 1.213. 52pp.

428295-04C Dickerson, C. W. May 24, 1993. Testing of a Paraffinized Block Rodenticide in Wild Norway Rats. Volume 6. Experiment #62-929. Purina Mills, Inc. Unpublished Report. OPP Designation 1.213. 48pp.

433753-01C Dickerson, C. W. April 16, 1994. Efficacy Study #961. Volume 1. Experiment #62-961. Purina Mills, Inc. Unpublished Report. OPP Designation 1.213. 50pp.

433753-02C Dickerson, C. W. April 26, 1994. Efficacy Study #966. Volume 2. Experiment #62-966. Purina Mills, Inc. Unpublished Report. OPP Designation 1.213. 49pp.

Good Laboratory Practices: Yes

Branch Chief: Meredith Laws

Team Leader: John Hebert, Product Manager 07

IRB Reviewer: Geraldine R. McCann, Biologist

BACKGROUND: The original application for the registration for this product from PM Resources, 67517-66 (602-357) dated June 15, 1993, did not have a cover letter attached or it was lost. The Volume 4 of the original efficacy studies (see above) was rejected and came back later with an MRID number (428643-01) that was out of sync from the original submission. The letter to R. Forrest from K. Kraft dated July 26, 1993, explains the change. In B. Jacobs review dated August 31, 1993, he does not catch the MRID change; therefore, he may refer to the number in the series as 428295-01. The PM Resources, Inc. requested transfer of the products to them from the originating company (Purina Mills, Inc.) September 5, 1996.

DISCUSSION: In his review dated August 31, 1993, B. Jacobs states: The efficacy reports state that the test substance was a 'Paraffinized Block Rodenticide'. In the CSF, [REDACTED] should be replaced with [REDACTED] [REDACTED] That information was changed on the current CSF for the product dated April 22, 1998. He goes on to state: "The efficacy reports summarize the results obtained in the laboratory trials using wild-type Norway rats and Purina's laboratory-raised house mice as subjects. One test for each species was run with fresh bait and the other with bait which had been "weathered" by keeping it for 15 days in an environment which, according to specifications in EPA's Protocols 1.213 and 1.214, is supposed to maintain a temperature of approximately 100° F with a relative humidity of 90-100%. Purina used a 3-day bait exposure period test instead of a 2-day test and B. Jacobs found this acceptable. The rats and mice were all caged individually for these tests. The MRID(s) offer no specifics of how the daily test routine was conducted, only an outline with references to SOP's and protocols. The first four test results are found in Table 1 below. In the rat trials, 85% of the rats died on the second day of testing and no control animals died. The rat tests were not run concurrently. "The bait that was offered to the rats was less than 1/3 of the 50 g specified in the protocol; however, Bromethalin is so toxic to rats and induces anorexia" very quickly which limits the amount of toxic bait rats will ingest. This didn't seem to affect the overall acceptance by rats in either test. B. Jacobs states that he is "not sure the test with weatherized bait tested what it was supposed to." He accepted the bait conditionally that Purina provide more information. about the weathering of the bait to the protocol specifications of temperature (100° F) and humidity (90-100%).

"In the mouse trials, all the mice exposed to the weathered bait died by Day 2. Bait acceptance in the fresh bait test was very erratic and was relatively low among the animals that took more than 2 days to die." (B. Jacobs, page 3-4, dated 8/31/93).

Table 1. Results of the Studies submitted to support Purina Assault All Weather Bait (67517-66) for Reregistration.

Test MRID Numbers	Subject #s	Sex Species	Toxic Bait Eaten (g)	OPP Diet Eaten (g)	Bait Acceptance Rate (%)	Mortality Results (%)	Days to Death (Day 1/Day 2)
42829504* 62-929	20	B*** Rats	177.7	47.6	86.7	100	1-3 (1/17)
42829503** 62-920	20	B Rats	144.3	66.3	74.8	100	1-3 (2/17)
42829502* 62-908	20	B Mice	18.1	27.9	60.7	95	1-5 (1/12)
42864301** (42829504) 62-909	20	B Mice	24.6	2.6	91.1	100	1-2 (6/14)

* Test was with fresh bait described on CSF dated 6/15/93

** Test was with weathered bait described by CSF dated 6/15/93

*** B stands for Both sexes.

The CSF dated 6/15/93 was not accepted by B. Jacobs because the type of wax was not specified as “XXXXXXXXXX”. The laboratory efficacy studies with the fresh bait were acceptable. The laboratory studies with the weathered bait were not acceptable because of the “departures from the prescribed conditions of 90-100% Relative humidity and approximately 100° F in temperature.” B. Jacobs did accept the “weather-resistance” claim on the label under the condition that more tests be submitted to confirm the weathering technique was done properly (page 7 of the review dated 8/31/93).

DISCUSSION

B. Jacobs review dated 3/27/95 (page 2) describes the rat study (MRID 433753-01) submitted to support the weather-resistance claims on the label. This study was conducted according to OPP Designation 1.213, and Purina “appropriately adapted the anticoagulant method to the needs for testing this product by shortening the bait exposure period from 15 to 2 days (as is used in the current version of the acute dry bait method for commensal rats, Protocol 1.209).” They shortened the mouse test (MRID 433753-02, OPP Designation 1.214) to 2 days as well. The results of the tests for both species follows:

Table 2. Results of the Studies submitted to support Purina Assault All Weather Bait Wax Bait Studies (67517-66) for Reregistration.

Test MRID Numbers	Subject #s	Sex Species	Toxic Bait Eaten (g)	OPP Diet Eaten (g)	Bait Acceptance Rate (%)	Mortality Results (%)	Days to Death (Day 1/Day 2)
433753-01* 62-961	20	B** Rats	128.8	333.9	32.9	95	2-4 (0/6)
433753-02* 62-966	20	B Mice	17.1	28.4	49.8	90	1-3 (6/9)

* Test was with weathered bait described by CSF dated 9/14/94

** OB stands for Both sexes

“The data indicate that the performance criterion of 80% mortality for tests with weathered bait was exceeded for both species.” The CSF dated 4/22/98 is acceptable for this product.

In B. Jacobs review dated 4/7/97, he states that “Prior efficacy review noted that data adequate to support the claims made for this product have been accepted by EPA. No further efficacy data are needed at this time.”

The use of sewers and burrows on the label was approved by D. Peacock and others 11/19/99.

Efficacy Comments

1. The efficacy reports submitted for this product reregistration have been found acceptable.
2. No verification could be determined for the freshness of the challenge diet used in the bioassays. This may have been the reason for the high consumption rates of toxic baits in the trials.
3. All of the studies were done with the minimum of animals without repeating the test. As called for in the guidelines, one more group of animals should have been used to verify the results and all raw data to account for the animals and test facilities should be attached to future submissions.

Conclusion(s)

With the omission of basic test information, a complete picture of the testing cannot be verified; however, I agree the W. Jacobs conclusions from his reviews dated 8/31/93, and 3/27/95:

“The laboratory efficacy studies of unweathered bait are acceptable, despite the erratic acceptance pattern among mice, particularly females.” and “The efficacy reports of tests of experimentally weathered product are acceptable.

Label	On the label for 67517-66: Don't use "days" as an optional word. Mice are
Comment(s)	nocturnal and unless forced will generally feed at night.

The specific statement on the front panel should be changed to read:

"Rodents consume a lethal dose in a single feeding with dead rodents appearing about 2 days after bait consumption begins. Rodents cease feeding after consuming a lethal dose. ASSAULT ALL WEATHER BAIT is effective against anticoagulant-resistant rats and mice."